UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

KEALANI DISTRIBUTION, LLC, *et al.*, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 4:22-cv-00856 (SDJ)

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

In 2016, the U.S. Food and Drug Administration ("FDA") promulgated a rule ("the Deeming Rule") that deemed e-cigarettes and other tobacco products to be subject to the requirements of the Family Smoking Prevention and Tobacco Control Act ("TCA"), including premarket authorization requirements for new tobacco products. The agency concluded that extending the TCA's requirements through the Deeming Rule would impose substantial costs on small businesses, and it predicted that manufacturers of "e-liquids"—the nicotine-containing liquid used in e-cigarettes—would pull between 50% and 87.5% of their products from the market rather than face the significant costs of seeking authorization.

Plaintiffs—several e-liquid manufacturers and a trade association espousing concerns about the cost of such applications—do not challenge the Deeming Rule. Instead, they challenge FDA's Premarket Tobacco Product Applications and Recordkeeping Requirements final rule ("Final Rule"), which was promulgated in 2021 to streamline and clarify the statutory premarket application process. Plaintiffs contend that the Final Rule violated the Regulatory Flexibility Act ("RFA"). Specifically, they attack FDA's certification that the rule would not have a significant economic impact on a substantial number of small entities ("Certification")—a certification which excused the agency from conducting a regulatory flexibility analysis under the RFA.

But Plaintiffs' claim fails for three independent reasons. *First*, the RFA's requirements are purely procedural, and Plaintiffs have not identified a procedural defect in FDA's Certification. Instead, they dispute the factual basis underlying that Certification—a challenge that is beyond the scope of judicial review under the RFA. *Second*, even if the Court were to review that factual basis, Plaintiffs offer no sound reason to doubt it, and they have failed to identify *any* provision of the Final Rule that substantially increased small entities' costs beyond those that were imposed by the TCA

and extended to Plaintiffs' products through the Deeming Rule. Therefore, the Certification would withstand review, and it is unclear how Plaintiffs' requested relief—which includes deferred enforcement of the Final Rule against Plaintiffs – would even benefit them, because it would not relieve them of their obligation to seek premarket authorization under the TCA pursuant to the Deeming Rule.

Third, even if Plaintiffs' challenge to the Certification had merit, their claim would still fail. That is because FDA, in promulgating the Final Rule, *also* conducted the complete regulatory flexibility analysis the RFA requires in the absence of a certification. And Plaintiffs do not quibble with that analysis. Therefore, they cannot establish an RFA violation. For all these reasons, Defendants' cross-motion for summary judgment should be granted, and Plaintiffs' motion for summary judgment denied.

BACKGROUND

I. Statutory and Regulatory Background

A. The Regulatory Flexibility Act

Congress passed the RFA to encourage administrative agencies to consider the potential impact of nascent federal regulations on small businesses. *Assoc. Fisheries of Maine v. Daley*, 127 F.3d 104, 111 (1st Cir. 1997).[1] Under the statute, whenever an agency is obliged to publish a notice of proposed rulemaking, it must also publish in the Federal Register an initial regulatory flexibility analysis addressing specific topics. *See* 5 U.S.C. § 603(a), (b). Similarly, when an agency promulgates a final rule, it must publish a final regulatory flexibility analysis. *Id.* § 604(a). The final analysis must address topics including any "significant issues raised by the public comments in response to the initial regulatory flexibility analysis"; "a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no

[1] Except where otherwise noted, in all quotations, emphases have been added, and internal alteration marks, citations, and footnotes have been omitted.

such estimate is available"; "a description of the projected . . . compliance requirements of the rule"; and "a description of … why … other significant alternatives to the rule considered by the agency which affect the impact on small entities [were] rejected." *Id.*

The analyses called for by 5 U.S.C. §§ 603 and 604 are not required "if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." *Id.* § 605(b). Such a certification must be published in the Federal Register at the same time the proposed or final rule is published, and it must be accompanied by "a statement providing the factual basis for . . . [the] certification." *Id.*

B. Premarket Authorization for New Tobacco Products

The TCA established a comprehensive scheme for the regulation of tobacco products predicated on Congress's finding that youth use of such products "is a pediatric disease of considerable proportions." Pub. L. No. 111-31, div. A, § 2(1), 123 Stat. 1776, 1777 (2009); *see generally Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 444 (5th Cir. 2020) ("Obviously the TCA's purpose sounds in (1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products."). As relevant here, the TCA makes it unlawful for a manufacturer to introduce into interstate commerce any "new tobacco product" unless the manufacturer applies for and obtains premarket authorization from FDA. 21 U.S.C. § 387j(a)(1)-(2). A "new tobacco product" is a tobacco product that was not commercially marketed in the United States as of February 15, 2007, or that was modified after that date.

The TCA provides that FDA "shall deny" an application to market a new tobacco product unless the agency finds that, based on "the information submitted to [FDA] as part of the application and any other information before [FDA] with respect to such tobacco product, permitting such tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2). The TCA requires that a

premarket tobacco product application ("PMTA") include "full reports of all information . . . concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products." 21 U.S.C. § 387j(b)(1)(A). PMTAs must also include "a full statement of the components, ingredients, additives, and properties" of the tobacco product; "the methods used in, and the facilities and controls used for, the manufacture" of the product; "specimens of the labeling proposed to be used" for the product; and "such other information . . . as the Secretary may require." 21 U.S.C. § 387j(b)(1)(B), (C), (F), (G).

In addition, applicants are aware that FDA examines PMTAs for information about the product's "risks and benefits to the population as a whole," taking into account the "likelihood that existing users of tobacco products will" quit or significantly reduce their use of more harmful tobacco products and the "likelihood that those who do not use tobacco products will start." *Id.* § 387j(c)(4). Applicants are further aware that FDA's ultimate determination "shall, when appropriate, be determined on the basis of well-controlled investigations" and other "valid scientific evidence." *Id.* § 387j(c)(5)(A), (B).

C. The Deeming Rule's Predicted Impact on Small Entities

In promulgating the Deeming Rule in 2016, FDA exercised its statutory authority to subject e-cigarettes and other products made or derived from tobacco to the TCA's requirements. *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016); *see also* 21 U.S.C. § 387a(b); *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 273 (D.C. Cir. 2019). Consequently, any deemed tobacco products that meet the TCA's definition of a "new tobacco product"

cannot lawfully be marketed without FDA premarket authorization after the rule's effective date of August 8, 2016.[2]

FDA also completed a Regulatory Impact Analysis ("Deeming Rule RIA") that predicted the Deeming Rule would have a significant economic impact on a substantial number of small entities. FDA024039.[3] The agency acknowledged that the "submission of premarket tobacco applications" would be "a costly requirement for [e-cigarette] manufacturers." FDA024043. It estimated that, for each small e-cigarette product manufacturer, that cost would be roughly $814,000 to $1.1 million in the first year alone. FDA024044.

FDA arrived at this estimate in part by analyzing the TCA's requirements for PMTAs, *see* FDA023996-024003, which the agency broke down into four "main categories": design and manufacturing information; toxicological studies; human studies; and hours spent by an entity's staff preparing the PMTA, FDA023997. The agency also accounted for the cost of an environmental assessment. FDA024000. FDA further recognized that human studies—which would assess the product's "health impacts" and "how people view and use the product"—would be particularly expensive "because some amount of research on the specific products . . . will typically be required" to obtain authorization. FDA023997-98.

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[2] For e-cigarettes already on the market as of August 8, 2016, FDA announced that it generally would not take enforcement action based on a product's lack of premarket authorization for several years. Deeming Rule, 81 Fed. Reg. at 28,978. Applicants were ultimately required to submit PMTAs by September 2020. *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019); Order, *American Acad. of Pediatrics v. FDA*, No. 18-883 (D. Md. Apr. 22, 2020), ECF No. 182.

[3] Bates-numbers with the prefix "FDA" refer to documents in the Deeming Rule administrative record and supplemental administrative record, all of which are included as part of the administrative record in this case. Bates-numbers with the prefix "F-" refer to documents in the administrative record post-dating the Deeming Rule that concern the PMTA Final Rule, and Final Rule RIA, or documents that are cited therein.

FDA predicted that the substantial cost of compiling PMTAs would reshape the market for deemed products by prompting "significant product exit and reduced entry." FDA023931; *see also* FDA023986 (products with "small-batch production" and "low volume products . . . will exit the market as a result of this rule"). In fact, the agency assumed that an especially large share of e-cigarette products, including between 50% and 87.5% of e-liquids, would exit the market due to the costliness of submitting a PMTA. FDA023990. This analysis was found to "compl[y] with the procedural requirements of the Regulatory Flexibility Act" outlined in 5 U.S.C. § 604(a). *Nicopure Labs, LLC v. FDA*., 266 F. Supp. 3d 360, 408 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019).

D. The PMTA Final Rule and Its Predicted Impact on Small Entities

In September 2019, FDA published the proposed Premarket Tobacco Product Applications and Recordkeeping Requirements rule. 84 Fed. Reg. 50,566 (Sept. 25, 2019).[4] The proposed rule set forth recordkeeping requirements for manufacturers, postmarket reporting requirements, and the procedures for evaluating PMTAs. *Id.* FDA also proposed "requirements related to the content and format of PMTAs," the "main focus" of which would be "the threshold amount of information necessary for application filing." *Id.* at 50,567. The agency crafted these proposals based on its experience reviewing "thousands of premarket applications that range widely in the level of detail they contain."*Id.*

FDA made clear, though, that it was not issuing requirements regarding "every piece of information necessary to receive a marketing order." 84 Fed. Reg. 50,566, 50,567. This was because FDA believed that "applicants have some flexibility in the types of scientific information they can submit" to meet the statutory standard. *Id.* FDA

[4] The proposed rule appears in the administrative record at F-002362. The Final Rule appears at F-018698.

predicted that the rule "would generate net benefits or negligible costs for most affected small entities" and therefore proposed to certify that the rule would not have a significant economic impact on a substantial number of small entities. *Id.* at 50,629.

After reviewing comments on the proposed rule, including its proposed certification, FDA published the Final Rule in October 2021. 86 Fed. Reg. 55,300 (Oct. 5, 2021). As the agency explained, the rule was intended to "improve the efficiency of the submission and review of PMTAs," in part by "provid[ing] applicants with a better understanding of the information a PMTA must contain." *Id.* For example, the Final Rule specified the sections into which an application should be organized, *id.* at 55,414; established formatting requirements, *id.* at 55,414-15; and identified informational requirements, including a "description of how marketing of the new tobacco product would" meet the statutory standard and a summary of any "restrictions on the sale, distribution, advertising, or promotion of the new tobacco product that the applicant proposes," *id.* at 55,415, 55,419. Because FDA determined that the Final Rule would generate either net benefits or negligible costs for most affected businesses, it certified that the rule would not have a significant economic impact on a substantial number of small entities. *Id.* at 55,405.

FDA published a regulatory impact analysis with the Final Rule ("Final Rule RIA"), which included the factual basis underlying the agency's Certification. *See* F-022768-811. The Final Rule RIA distinguished between the impacts attributable to the Deeming Rule versus the Final Rule, and only "estimate[d] the incremental impact of [the Final Rule] relative to the compliance costs attributable to the Deeming Final Rule." F-022779. FDA reiterated its prediction, which it made in promulgating the Deeming Rule, that by causing "all premarket requirements [to] apply to deemed new tobacco products,"*id.*, the Deeming Rule would prompt "[s]ome small firms [to] exit the market or merge with other firms to afford . . . compliance costs," F-022809. While this would constitute "a significant impact on a substantial number of small entities," that impact

was "attributable to the Deeming Rule and not this final rule." *Id*. On the same reasoning, the agency disagreed with commenters who attributed substantial costs to the Final Rule, explaining that they had "conflate[d] the impacts of the Deeming Rule with the impacts of this final rule" by failing to recognize the application costs that were "already accounted for" in the Deeming Rule RIA. F-022780; *see also supra*, pp. 5-6 (summarizing costs identified in the Deeming Rule RIA).

FDA nonetheless acknowledged the Final Rule had introduced "some new requirements for PMTAs." F-022795. These include certain "content and format" requirements, F-022774, which "[i]ncreas[e] the administrative effort required to organize and prepare a PMTA," F-022795. But FDA explained that the costs of those new requirements represent a relatively small increase over those arising from the Deeming Rule. *See* F-022801, Table 24 (comparing the estimated cost to compile a PMTA before and after the Final Rule). For example, the agency estimated that the cost to submit a PMTA for e-liquid products would increase only about 2% to 2.5%—that is, from $1.16–1.19 million before the Final Rule to $1.19–1.21 million after the Final Rule. *Id*.[5] Thus, the Final Rule represented only an "incremental change" in the burden to submit PMTAs. F-022780.

Moreover, the agency predicted that this modest cost increase would be offset by savings and increased profits for most affected entities. F-022797. Those savings flow from the Final Rule's clarification and streamlining of the submission-and-review process, which help applicants to avoid costly supplemental applications. *See* F-022783 (discussing the goal of avoiding applicant "trial and error"). This increased efficiency

[5] Costs estimated in the Final Rule RIA were in 2019 dollars, whereas costs estimated in the Deeming Rule RIA were in 2014 dollars. For that reason, when FDA relied on estimates from the Deeming Rule RIA in drafting the Final Rule RIA, it adjusted for inflation. *See, e.g.*, F-022786.

would also enable some applicants to obtain marketing orders (and revenue from authorized products) more quickly. *Id.*

For all these reasons, the Final Rule RIA concluded that the Final Rule would not have a significant impact on a substantial number of small entities. F-022808.

II. Plaintiffs' Lawsuit

Plaintiffs are small manufacturers of e-liquids and a trade association. Compl. (ECF No. 1) ¶¶ 1-2. They complain that PMTA requirements have rendered many e-cigarette product manufacturers "unable to prepare an application" while forcing others "to substantially narrow the proportion of their products for which marketing approval is sought." *Id*. ¶ 2. Yet despite this, and despite FDA's prediction that the Deeming Rule would cause manufacturers of e-liquids to pull between 50% and 87.5% of their products rather than face the cost and burden of compiling PMTAs, FDA023990, Plaintiffs never challenged the Deeming Rule on those grounds, and their time to do so has expired.[6]

Instead, Plaintiffs have challenged the Final Rule, alleging that it "imposes a significant impact on every small entity." Compl. ¶ 62. Plaintiffs' sole claim is that FDA violated the RFA because its Certification was "erroneous." Compl. ¶ 66. Plaintiffs do not challenge any other aspect of the Final Rule or the procedures that led to its promulgation. *See generally* Compl.

On January 2, 2024, Plaintiffs filed a motion for summary judgment. Pls.' Mot. for Summ. J. (ECF No. 36) ("Mot."). They seek a declaration that the Final Rule violated the RFA; remand of the rule to the agency; and an injunction prohibiting FDA "from enforcing the PMTA requirements against any named plaintiff or member of the

[6] The statute of limitations for such a challenge lapsed in 2022, prior to the filing of this lawsuit. *See* 28 U.S.C. § 2401(a) (establishing a six-year limitations period to challenge agency action).

[United States Vaping Association], until FDA has complied with the RFA." *Id.* at 20-21.[7] Defendants now oppose that motion and cross-move for summary judgment.

LEGAL STANDARD

"When the court reviews a federal administrative agency's decision, a motion for summary judgment stands in a somewhat unusual light, in that the administrative record provides the complete factual predicate for the court's review." *Exxon Mobil Corp. v. Mnuchin*, 430 F. Supp. 3d 220, 228 (N.D. Tex. 2019). "The standard set forth in Rule 56(c) does not apply." *Yogi Metals Grp. Inc. v. Garland*, 567 F. Supp. 3d 793, 798 (S.D. Tex. 2021), aff'd, 38 F.4th 455 (5th Cir. 2022). Instead, "summary judgment serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with" the relevant standard. *Id.*; *see also Bank of Commerce of Laredo v. City Nat. Bank of Laredo*, 484 F.2d 284, 289 (5th Cir. 1973) (The "standard for … [review on an administrative record] is that established by the legislation authorizing the agency action" and the "Administrative Procedure Act").

The RFA authorizes courts to review agencies' compliance with 5 U.S.C. §§ 604 and 605(b) under the Administrative Procedure Act. 5 U.S.C. § 611(a) (permitting review "in accordance with [Title 5, chapter 7] of the United State Code"). Such review is limited "only to determin[ing] whether an agency has made a reasonable, good faith effort to carry out the mandate of the RFA," which is "procedural rather than substantive." *Alenco Commc'ns, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000).

STATEMENT OF THE ISSUES TO BE DECIDED

Whether, in promulgating the Final Rule, FDA made a reasonable, good faith effort to carry out the procedural mandate of the RFA.

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[7] Plaintiffs' Complaint also refers, in passing, to vacatur of the Final Rule. Compl. ¶67. However, Plaintiffs' prayer for relief (Compl. 19) and motion for summary judgment (Mot. 20-21) abandoned that request.

ARGUMENT

Plaintiffs' claim fails for three independent reasons. First, FDA satisfied the RFA by considering whether the Final Rule would have a significant impact on a substantial number of small entities and then certifying, together with a factual basis, that it would not. Because Plaintiffs have failed to identify a procedural defect in that Certification, their claim fails. But second, even if the Court reviews the rationale underlying that Certification, Plaintiffs challenge would still fail because the agency's factual conclusions were reasonable. And third, even if Plaintiffs' attack on the Certification had merit (which it does not), they still could not establish an RFA violation because FDA *also* conducted an analysis that satisfies 5 U.S.C. § 604(a), which Plaintiffs have not attacked.

I. FDA's Certification Satisfies The RFA

A. Plaintiffs identify no procedural defect in FDA's Certification

The Fifth Circuit has made clear that the RFA's mandate is "procedural rather than substantive." *Alenco*, 201 F.3d at 625. Thus, "[t]he statute simply requires agencies to publish analyses that address specific topics, and if [an agency] does so, it has complied with the Regulatory Flexibility Act." *Nicopure*, 266 F. Supp. 3d at 408; *see also Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) (noting that, while the RFA "directs agencies to state, summarize, and describe, the [statute] in and of itself imposes no substantive constraint on agency decision-making"). Thus, a court "does not review the factual substance of" a certification under 5 U.S.C. § 605(b), nor whether the agency "reached the 'correct' determination." *Grocery Servs., Inc. v. USDA Food & Nutrition Serv.*, No. H-06-2354, 2007 WL 2872876, *10 (S.D. Tex. Sept. 27, 2007). Rather, the question is "whether the agency followed the procedural steps set out in the RFA." *Id*.

Here, FDA followed the RFA's procedural requirements because it "publish[ed] [its] certification in the Federal Register" with the Final Rule and offered "a statement providing the factual basis for such certification." 5 U.S.C. § 605(b). As discussed above, the Final Rule RIA explained that the significant costs associated with submitting PMTAs were traceable to the Deeming Rule; the new administrative burdens imposed by the Final Rule were incremental and modest compared to the baseline costs the agency had already considered in the Deeming Rule RIA; and those new costs would be offset by greater efficiencies and earlier revenues for most affected entities. *See supra* pp. 7-9 (discussing F-022768-811). The RFA was therefore satisfied. *See Grocery Servs.*, 2007 WL 2872876, at *10 (holding that an agency had satisfied § 605(b) because it "published its certification in the Federal Register and provided a factual basis" for it); *see also Nat'l Rest. Ass'n v. Solis*, 870 F. Supp. 2d 42, 60 (D.D.C. 2012) (because the RFA's requirements are "purely procedural," an agency "complied . . . when it concluded that . . . the rule would not have an impact on a substantial number of small entities" and provided a factual basis).

Plaintiffs "fail[s] to articulate specific *procedural* flaws" in FDA's Certification. *Alenco*, 201 F.3d at 625. Plaintiffs baldly assert that FDA did not provide a factual basis for certification, Mot. 17, but the face of the agency's decision proves otherwise, *see supra* pp. 7-9 (discussing F-022768-811). Indeed, in the same breath, Plaintiffs acknowledge and dispute aspects of the agency's factual analysis. *See* Mot. 16-17 (debating FDA's factual "claim[]" that the burden of compiling a PMTA emanates from the Deeming Rule and its further "rationale" that the Final Rule would confer "benefits on applicants"). That Plaintiffs "disagree with [FDA's] analysis" of certain factual issues "does not mean that [FDA] failed to meet its obligations [under the RFA] to examine and discuss" them in supporting its Certification. *ValueVision Int'l, Inc. v. FCC*, 149 F.3d 1204, 1213 (D.C. Cir. 1998).

Plaintiffs' reliance (Mot. 17) on *North Carolina Fisheries Association, Inc. v. Daley*, 16 F. Supp. 2d 647 (E.D. Va. 1997), is unavailing. In that case, there was "no evidence in the Administrative Record . . . showing that [the agency] ha[d] at least considered" the present effects of the regulatory requirement at issue. *Id.* at 652. In sharp contrast, here FDA distinguished the impacts of the Final Rule from those of the Deeming Rule and TCA; considered the incremental additional burdens and costs flowing from the Final Rule; analyzed the Final Rule's benefits and their potential to offset its incremental costs; and concluded, in light of all of this, that the Final Rule would not have a significant impact on a substantial number of small entities. *See supra* pp. 7-9 (discussing F-022768-811).

Plaintiffs' remaining arguments take issue not with the procedural steps undertaken by FDA but with the accuracy of the agency's factual analysis. "In other words, plaintiffs challenge the factual veracity of the" agency's analysis, which "is outside the limited scope of judicial RFA review." *Grocery Services*, 2007 WL 2872876 at *10 (refusing to entertain plaintiffs' dispute of the factual conclusion underlying an agency's § 605(b) certification); *see also Council for Urological Interests v. Burwell*, 790 F.3d 212, 227 (D.C. Cir. 2015) (holding that an agency's statement of belief as to a rule's impact satisfied §605(b)'s requirements, notwithstanding plaintiff's argument that this belief was "incorrect").

B. In any event, FDA's Certification has adequate factual support

While the Fifth Circuit in *Alenco* limited RFA review to compliance with the statute's "purely procedural" requirements, 201 F.3d at 625, at least one district court in this circuit, and some courts outside of this circuit, have also reviewed the factual basis underlying a § 605(b) certification. When undertaken, however, such review looks only for a "reasonable, good faith effort" to comply with the RFA and it is "highly deferential" to the agency's analysis, "particularly with regard to [the] agency's

predictive judgments about the likely economic effects of a rule." *Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 941 (N.D. Miss. 2016) (quoting *Helicopter Ass'n Int'l, Inc. v. FAA*, 722 F.3d 430, 432–33 (D.C. Cir. 2013)); *see also Council for Urological Interests*, 790 F.3d at 227 ("So long as the procedural requirements of [a § 605(b)] certification are met," a "court's review is 'highly deferential' as to the substance of the analysis.").

Here, even if the Court accepts Plaintiffs' invitation to review the factual basis of FDA's Certification, it easily withstands review for multiple reasons. *First*, in explaining its Certification, FDA reasonably attributed the "costs that result from the requirement to prepare and submit PMTAs for deemed new tobacco products to" the Deeming Rule rather than the Final Rule. F-022779. That decision finds ample support in the Deeming Rule RIA, which comprehensively accounted for those costs. *See supra* pp. 5-6; *see also* F-022780 (referring readers to the Deeming Rule RIA as further support for the Final Rule RIA). It also makes sense, considering that the Final Rule "[p]rimarily . . . explains how to present and organize information already required by" the TCA and the Deeming Rule. F-022783. Thus, in the Final Rule RIA, FDA reasonably "estimate[d] the incremental impact" of the Final Rule "relative to the compliance costs attributable to" the TCA and Deeming Rule. F-022779.

In arguing that FDA failed to consider the Final Rule's true costs (Mot. 16-19), Plaintiffs "conflate[] the impacts of the Deeming Rule with the impacts of" the Final Rule, and they ignore that "the Deeming Rule [RIA] already accounted for" the costs about which they complain. F-022780. For example, Plaintiffs neglect how the Deeming Rule RIA concluded, just as Plaintiffs do, that studies concerning products' health impacts would be especially expensive for applicants. *Compare* FDA023997-98 (concluding that "health impact" and other "human studies" are a "relatively expensive part of the information required for PMTAs"), *with* Mot. 18 (arguing that "[o]ne of the most burdensome components of a PMTA is the preparation of health risk studies"). FDA explained in the Deeming Rule RIA that such studies would "typically be

required" for applicants to meet their statutory burden, and the Deeming Rule RIA accordingly accounted for their costs. FDA023998 (estimating a cost between $135,000 and $1.8 million per applicant).[8]

Contrary to Plaintiffs' suggestion (Mot. 19), the Deeming Rule RIA also accounted for the "costs of testing" and "environmental assessment." *See* FDA023997-98 (estimating the costs of "research and testing" by category); FDA024000 (estimating the cost of an environmental assessment to be $16,179 per product). And the Deeming Rule RIA additionally provided a comprehensive accounting of the four "main categories" of PMTA requirements, which Plaintiffs neither acknowledge nor attack. *See* FDA023997-98.[9] By neglecting the Deeming Rule RIA's cost analysis, Plaintiffs overlook much of the factual rationale behind FDA's Certification for the PMTA Final Rule.

Second, after concluding that the costs of studies presented in the Deming Rule RIA "continue to reflect the best available estimates" of that application cost, F-022780, the Final Rule RIA then analyzed the Final Rule's "new requirements" that were "not include[d] in the Deeming [Rule RIA]." F-022793, 022795. FDA explained that the Final Rule requires additional "administrative effort" from applicants, such as "an application summary." F-022795. FDA assumed that these additional requirements

[8] This analysis of human studies' costs also negates Plaintiffs' contention (Mot. 19) that the Deeming Rule RIA ignored those costs and implied that applicants could instead rely on "public information" and "studies the FDA *itself* was conducting." The Deeming Rule RIA referred to these as mere "example[s]" of human studies on which applicants may be able to rely without suggesting they would eliminate the need to conduct original studies as well. FDA024060.

[9] Plaintiffs also fail to acknowledge the Deeming Rule RIA's prediction that the Deeming Rule would cause manufacturers to pull between 50% and 87.5% of their products from the market, FDA023990, even though Plaintiffs' own experiences bear out that prediction, *see* Compl. ¶ 7 (alleging Kealani could only afford to submit PMTAs for 10% of its e-liquid products); ¶ 8 (alleging Diamond Vapor had to "severely limit the proportion of [its e-liquid] products that can be submitted for individual testing"), ¶¶ 9-11 (similar).

would increase applicants' "administrative cost" by 50% on average. *Id.* Because administrative costs account for a relatively small portion of the total costs to compile a PMTA, *see, e.g.*, FDA023998, Table 11(a) ("administrative staff hours"), this increase had a relatively small impact on applicants' *total* application costs. All of this is reflected in FDA's estimate of how much the total cost of preparing a PMTA would increase after the Final Rule. *See* F-022801, Table 24 (estimating a roughly 2% to 2.5% increase in total costs). That "predictive judgment[]" merits significant deference. *Am. Health Care Ass'n*, 217 F. Supp. 3d at 941.

Yet Plaintiffs ignore this aspect of FDA's analysis. For example, they mistakenly suggest that neither the Deeming Rule RIA nor the Final Rule RIA accounted for the cost for applicants to submit marketing plans. *See* Mot. 19. But the Final Rule RIA acknowledged applicants' need to provide "a description of their" marketing plans and "account[ed] for the incremental burden of" that cost in the Final Rule RIA. F-022795.

Third, the Final Rule RIA predicted that the Final Rule would also confer offsetting benefits on most regulated entities. For example, the rule was intended to help applicants submit complete applications on their first attempt, thereby minimizing the need for costly follow-on applications. *See, e.g.*, F-022783 (explaining the "trial-and-error" inefficiencies the rule was intended to correct). In addition, the agency predicted that the rule would help some applicants obtain marketing authorization—and revenue from authorized products—significantly sooner. F-022797-98. The agency thus reasonably concluded that the Final Rule would confer a net economic "benefit," rather than a significant cost, for many entities. F-022810; *cf. ValueVision Int'l, Inc. v. FCC*, 149 F.3d 1204, 1213 (D.C. Cir. 1998) (agency's conclusion that a rule would have "a positive effect" on regulated entities satisfied the RFA). Plaintiffs barely acknowledge this rationale, *see* Mot. 16-17 (dismissing the rule's "efficiency benefits" as "incredibl[e]"), and they offer no reason to doubt—let alone override – FDA's "predictive judgment," *Am. Health Care Ass'n*, 217 F. Supp. 3d at 941.

More glaringly, Plaintiffs do not identify *any* specific provision of the Final Rule that substantially increased PMTA costs beyond those accounted for in the Deeming Rule RIA. In fact, Plaintiffs all but ignore the Final Rule's text,[10] focusing instead on inapt statements and authorities. Plaintiffs make much of FDA's acknowledgment in the Deeming Rule RIA that it "cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established." Mot. 7, 19, 20 (quoting FDA023965). But the agency's commonsense observation that it cannot predict the future does not undermine the Final Rule RIA, which assessed requirements that *have* been established. *See, e.g.*, F-022797-805 (predicting that costs would be modest and benefits significant). Plaintiffs also argue that the TCA left FDA with "discretion" to determine precise PMTA requirements, Mot 17; that "important issues" about those requirements remained undecided before the Final Rule, Mot. 18; and that FDA officials previously alluded to "rules of the road" yet to be established, Mot. 19. But none of this advances Plaintiffs' argument because, again, they identify nothing in the Final Rule that settled these issues in a way that substantially increased costs beyond those accounted for in the Deeming Rule RIA.[11] Thus, the factual analysis accompanying FDA's Certification represented a "reasonable, good faith effort" to comply with the RFA. *Alenco*, 201 F.3d at 625.

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[10] Even where Plaintiffs refer generally to the Final Rule's text, they exaggerate. They say the rule "takes over 100 pages to describe the PMTA requirements for vapor products," Mot. 12 (offering no citation), but the rule dedicates only about nine pages of substantive text to the "required content and format" of PMTAs. *See* 86 Fed. Reg. at 55,414-15, 55,419-21, 55,429-32 (excluding tables). And contrary to Plaintiffs' implication, *see* Mot. 12, FDA's analysis even accounted for firms' costs in hiring attorneys to review and advise on the Final Rule in its entirety, *see* F-022800.

[11] Plaintiffs further fault the Certification because it was not supported by an "economic analysis." Mot. 17. But "the RFA plainly does not require [an] economic analysis" even when an agency seeks to satisfy § 604(a), *Alenco*, 201 F.3d at 625, let alone when the agency merely seeks to satisfy § 605(b). Yet even if it the RFA did require such an analysis, FDA provided one. *See supra* pp. 7-9, *infra* pp. 18-19.

II. Even If FDA's Certification Under § 605(b) Was Defective, The RFA Was Satisfied Because FDA's Analysis Also Comports With § 604(a)

FDA's Certification under 5 U.S.C. § 605(b) that the Final Rule would not have a significant economic impact on a substantial number of small entities excused the agency from performing a regulatory flexibility analysis under 5 U.S.C. § 604(a). Nonetheless, while it abjured the need to do so, *see* F-022809, in the Final Rule RIA FDA *did* address each topic delineated in § 604(a). Because Plaintiffs have not attacked the agency's analysis of the topics in § 604(a), their claim that FDA violated the RFA fails even if their challenge to the § 605(b) Certification succeeds.

The Final Rule RIA reveals FDA's "reasonable, good faith effort" to comply with § 604(a). *Alenco*, 201 F.3d at 625. *First*, the agency explained "the need for, and objectives of, the" Final Rule. 5 U.S.C. § 604(a)(1). It did so in both the rule's preamble, *see, e.g.*, 86 Fed. Reg. at 55,301 ("Purpose of the Regulatory Action"), and in the Final Rule RIA, *see, e.g.*, F-0022783-84 (describing issues the rule was designed to address), F-022797-800 (discussing benefits of the rule). *Second*, FDA discussed "the significant issues raised by . . . comments" on its initial regulatory flexibility analysis, including the agency's "assessment . . . of such issues" and "any changes made as a result." 5 U.S.C. § 604(a)(2); *see* F-022779-80 ("Comments on the Preliminary RIA and Our Responses"), F-022781 ("Summary of Changes"). *Third*, and relatedly, the agency responded to the Small Business Administration's comment which, like Plaintiffs, argued that FDA had failed to account for some of the costs of compiling a PMTA. 5 U.S.C. § 604(a)(3); *see* F-22808-09 (discussing comment), F-022779-80 (offering responses).[12] *Fourth*, FDA explicitly "describe[d]" and "estimate[d] … the number of small entities to which the rule will

[12] Thus, Plaintiffs' contention that FDA failed to respond to the Small Business Administration's comment (Mot. 17 n.11) is simply wrong. And to the extent Plaintiffs fault that response for its brevity, "there is no requirement as to the amount of detail" that an RFA analysis must provide in responding to comments. *Little Bay Lobster Co., Inc. v. Evans*, 352 F.3d 462, 471 (1st Cir. 2003).

apply." 5 U.S.C. § 604(a)(4); *see* F-022809-10 ("Description and Number of Affected Small Entities").

Fifth, FDA detailed the Final Rule's "projected reporting, recordkeeping and other compliance requirements," as well as "the classes of small entities" affected and the "professional skills necessary" for compliance. 5 U.S.C. § 604(a)(5); *see, e.g.,* F-022783 (discussing recordkeeping requirements); F-022784, F-022800 (reporting requirements); F-002802-04, F-022808, F-022822 (costs of reporting requirements); F-22809 (describing the small entities subject to these requirements); F-022800-801, F-022809-10 (discussing firms' need to employ "regulations reviewers," including lawyers, to comply with these and other requirements in the rule); F-022785-86 (categorizing other professions required for compliance).

Finally, FDA discussed "steps . . . to minimize" the Final Rule's impact on small entities, and explained its "reasons for selecting the alternative adopted in the final rule and why . . . other . . . alternatives [were] rejected." 5 U.S.C. § 604(a)(6); *see, e.g.,* F-22807-808 (rejecting "regulatory alternatives" such as dispensing with "postmarket reporting" because of that requirement's "public health benefits"), F-022811 (discussing the same issue with respect to small entities), F-022797-800 (discussing the agency's effort to introduce offsetting benefits for all entities). Because FDA "completed a Regulatory Impact Analysis which contains a discussion of all of the required topics" listed in § 604(a), it "complied with the procedural requirements of the Regulatory Flexibility Act" regardless of whether its Certification satisfied § 605(b). *Nicopure*, 266 F. Supp. 3d at 408.

III. Any RFA Violation Should Not Exempt Plaintiffs From The Final Rule

Relief for a violation of the RFA may include "deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest." 5 U.S.C. § 611(a)(4)(B). Plaintiffs seek to enjoin "FDA from

enforcing the PMTA [Final Rule's] requirements against any named plaintiff or member of the [United States Vaping Association] until FDA has complied with the RFA." Mot. 21. Even if the Court finds an RFA violation here (and there is none), the public interest squarely favors continued enforcement of the Final Rule against Plaintiffs.

Deferring enforcement of the PMTA Final Rule against Plaintiffs would not suspend their obligation to seek premarket authorization for their products under the TCA, *see* 21 U.S.C. § 387j(a)(2), as made applicable to e-cigarette products by the Deeming Rule. In other words, Plaintiffs would remain subject to the costs and burdens of submitting PMTAs which, as evidenced by the Deeming Rule RIA (*see supra* pp. 5-6), predate the Final Rule. Deferring enforcement of the Final Rule would only introduce confusion into the regulatory process by suspending requirements designed to "improve the efficiency of the submission and review of PMTAs" based "on the experience the Agency has gained by reviewing . . . thousands of premarket applications." 86 Fed. Reg. at 55,301.

Moreover, relieving Plaintiffs from the TCA's premarket approval requirements would be contrary to the public interest. A "court sitting in equity cannot ignore the judgment of Congress, deliberately expressed in legislation," and "override Congress' policy choice . . . as to what behavior should be prohibited." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001) (quotation marks omitted). And Congress found that the public interest lay in prohibiting the marketing of a new tobacco product until a manufacturer submits a PMTA and FDA finds that the product will produce a net benefit to the public health. 21 U.S.C. § 387j(a)(2). This requirement was predicated on Congress's concern about youth tobacco product use, given that "[v]irtually all new users of tobacco products are under the minimum legal age to purchase" such products, and because "Congress's previous attempts to curb adolescent tobacco use had failed." *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 413-14 (4th Cir. 2022) (citing 123 Stat. at 1777).

Citing cost constraints, Plaintiffs have chosen not to submit PMTAs for many of their products. *See* Compl. ¶¶ 7-11. This was precisely the result that FDA predicted would flow from the Deeming Rule. *See, e.g.*, FDA023990. But the Deeming Rule's validity, and the requirements that flow from it, are not at issue here. Instead, Plaintiffs seek to defer their legal obligations—and continue profiting from unlawful products in the interim—by challenging the Final Rule, which introduced only an "incremental change" in the costs of a PMTA. F-022780. Under these circumstances, rewarding Plaintiffs' effort to bypass Congress's mandate would contravene, rather than serve, the public interest.

CONCLUSION

For the foregoing reasons, Defendants' Cross Motion for Summary Judgment should be granted and Plaintiffs' motion should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the CM/ECF system, and that service will be accomplished by that system on registered participants as identified on the Notice of Electronic Filing.

February 16, 2024

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